

## **4244 FIRST AID KIT- 4244 first aid kit**

**Honeywell Safety Products USA, INC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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## **4244 First Aid Kit (PVP wipes, alcohol wipes, Antiseptic Spray, ASA, ammonia- 340410FP)**

### **Povidone Iodine Swab**

#### **Active ingredient**

Povidone-iodine solution USP, 10% (equivalent to 1% titratable iodine)

### **Povidone Iodine Swab**

#### **Purpose**

First aid antiseptic

### **Povidone Iodine Swab**

#### **Uses**

- first aid to help prevent the risk of infection in minor cuts, scrapes, and burns

### **Povidone Iodine Swab**

#### **Warnings**

#### **For external use only**

#### **Do not use**

- over large areas of the body
- on individuals who are allergic or sensitive to iodine

#### **Ask a doctor before use if you have**

- deep or puncture wounds,
- animal bites
- serious burns

#### **When using this product**

- do not use longer than one week unless directed by a doctor

#### **Stop use and ask a doctor if**

- conditions persists or gets worse
- irritation and redness develops

#### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away

### **Povidone Iodine Swab**

#### **Directions**

Reverse cardboard sleeve, then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

- clean affected area
- apply to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard swab after single use

### **Povidone Iodine Swab**

#### ***Other information***

- store at room temperature away from light
- keep from freezing or excessive heat
- do not use if package is torn or open

### **Povidone Iodine Swab**

#### ***Inactive ingredients***

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

### **Povidone Iodine Swab**

#### ***Questions and comments***

1-800-430-5490

### **Alcohol Wipe**

#### ***Active ingredient***

Isopropyl alcohol 70%

### **Alcohol Wipe**

#### ***Purpose***

First aid antiseptic

### **Alcohol Wipe**

#### ***Uses***

- first aid to help prevent infection in minor cuts, scrapes, and burns

### **Alcohol Wipe**

#### ***Warnings***

#### **For external use only**

#### **Do not use**

- in the eyes
- over large areas of the body

#### **Ask a doctor before use if you have**

- deep or puncture wounds
- animal bites

- serious burn

**When using this product**

- do not use longer than one week unless directed by a doctor

**Stop use and consult a doctor**

- if condition persists or gets worse

**Keep out of reach of children**

- If swallowed, get medical help or contact a Poison Control Center right away.

**Alcohol Wipe*****Directions***

- clean the affected area
- apply wipe to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard wipe after single use

**Alcohol Wipe*****Other information***

store at room temperature 15<sup>0</sup> to 25<sup>0</sup> C (59<sup>0</sup> to 77<sup>0</sup>F)

**Alcohol Wipe*****Inactive ingredient***

water

**Alcohol Wipe*****Questions***

1-800-430-5490

**Antiseptic Spray*****Active ingredient***

Benzalkonium chloride 0.13%

**Antiseptic Spray*****Purpose***

First aid antiseptic

**Antiseptic Spray*****Uses***

- first aid to help prevent infection in minor cuts, scrapes and burns

**Antiseptic Spray*****Warnings***

**For external use only****Do not use**

- in or near the eyes
- over large areas of the body

**Ask a doctor before use if you have**

- deep or puncture wounds
- animal bites
- serious burns

**When using this product**

- do not use longer than one week unless directed by a doctor

**Stop use and ask a doctor if**

- the condition persists or gets worse

**Keep out of reach of children**

- If swallowed, get medical help or contact a Poison Control Center right away

**Antiseptic Spray*****Directions***

- clean the affected area
- spray a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

**Antiseptic Spray*****Other information***

- shake well
- store at room temperature 15<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup> -86<sup>0</sup> F)

**Antiseptic Spray*****Inactive ingredients***

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, trolamine, water

**Antiseptic Spray*****Questions***

1-800-430-5490

**Ammonia Inhalant*****Active ingredient***

Ammonia 15%

**Ammonia*****Purpose***

Respiratory stimulant

## **Ammonia**

### ***Uses***

- to prevent or treat fainting

## **Ammonia**

### ***Warnings***

**For external use only**

### **Do not use**

- if you have breathing problems such as asthma or emphysema

### **Stop use and ask a doctor if**

- condition persists

### **Keep out of reach of children**

If swallowed get medical help or contact a Poison Control Center right away.

## **Ammonia**

### ***Directions***

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapor

## **Ammonia**

### ***Other information***

- store at room temperature away from light

## **Ammonia**

### ***Inactive ingredient***

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

## **Ammonia**

### ***Questions***

1-800-430-5490

## **Aspirin**

### ***Active Ingredient***

Aspirin 325 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

## **Aspirin**

### ***Purpose***

Pain reliever/fever reducer

## **Aspirin**

### ***Uses***

temporarily reduces fever and relieves minor aches and pains associated with:

- a cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- premenstrual and menstrual periods

## **Aspirin**

### ***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

### **Stomach bleeding warning:**

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

### **Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer

### **Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have asthma

### **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout or arthritis

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- any new symptoms appear

**If pregnant or breast-feeding,**

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact Poison Control Center right away.

**Aspirin*****Directions***

- drink a full glass of water with each dose
- adults and children 12 years of age and older: take 1 or 2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24 hours
- children under 12 years of age: consult a doctor

**Aspirin*****Other information***

- store at room temperature 15° - 30°C (59° - 86°F)
- TAMPER EVIDENT PACKETS - DO NOT USE IF OPEN OR TORN

**Aspirin*****Inactive ingredients***

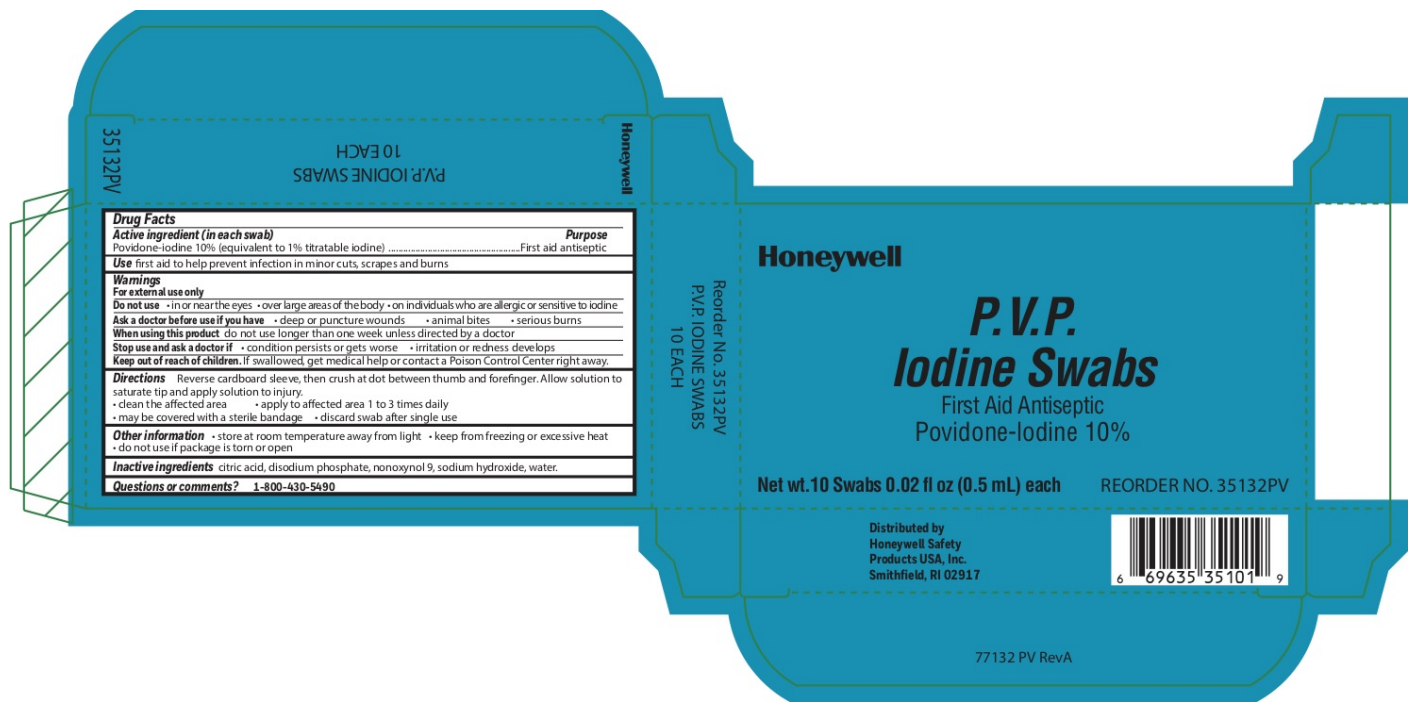
corn starch, croscarmellose sodium\*, hypromellose\*, microcrystalline cellulose\*, mineral oil\*, polyethylene glycol\*, povidone, propylene glycol, silicon dioxide, stearic acid\*, titanium dioxide\*

\*may contain these ingredients

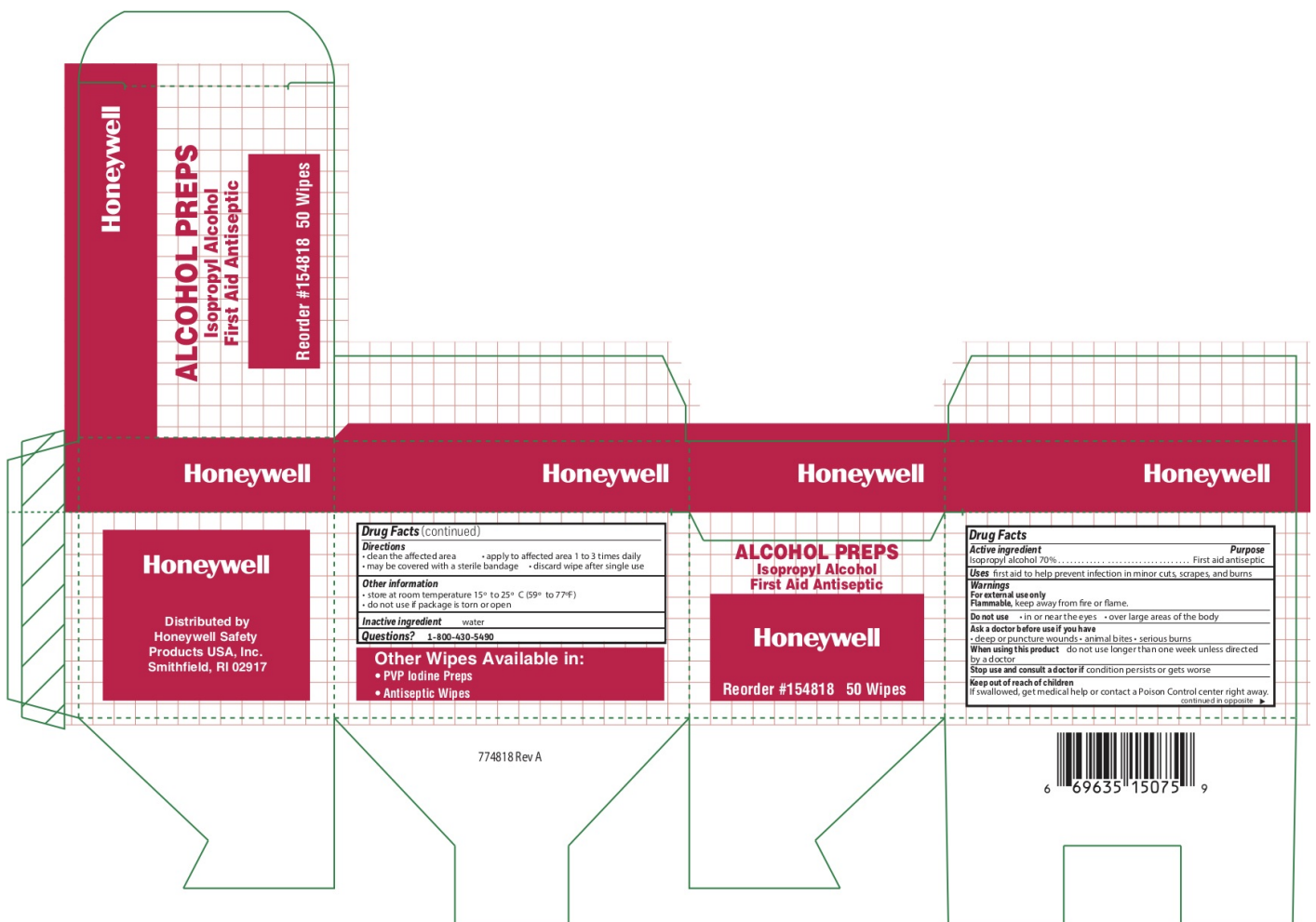
**Aspirin*****Questions or Comments?***

1-800-430-5490

**Povidone Iodine Swab*****Principal Display Panel***



## Alcohol Principal Display Panel



## Antiseptic Spray

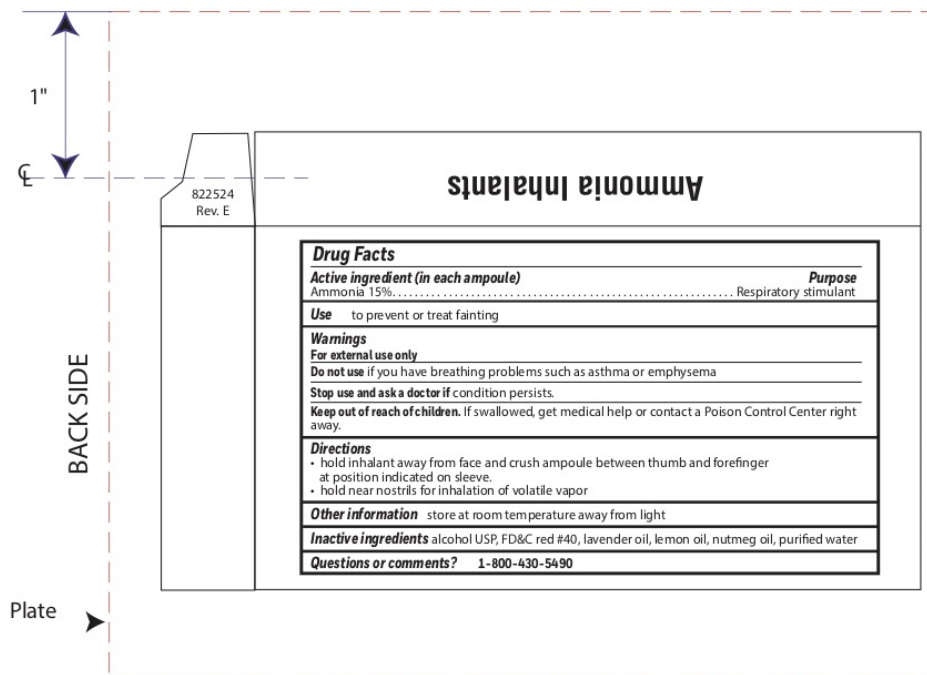
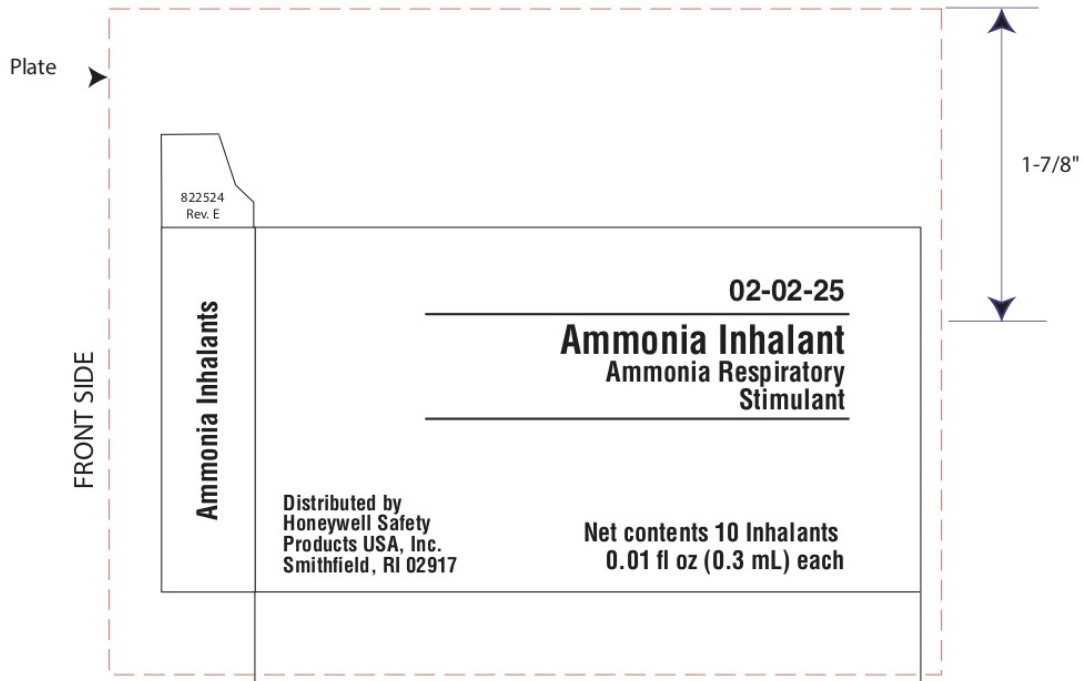


## Principal Display Panel

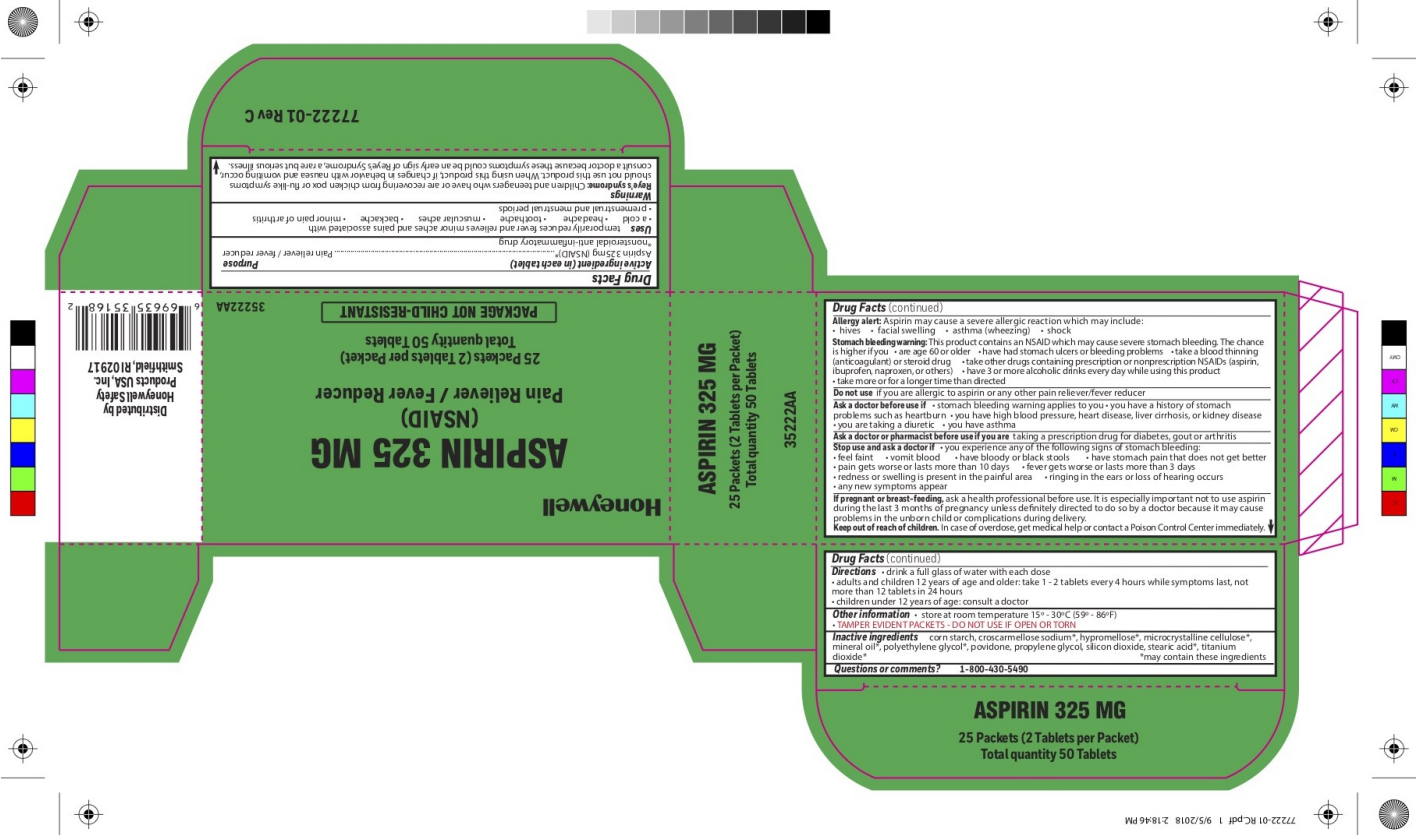
<b>Honeywell</b> 032203	<b>Drug Facts</b>
<b>ANTISEPTIC SPRAY</b>	<b>Active ingredient</b> Benzalkonium chloride 0.13% . . . . .
<b>Benzalkonium chloride</b>	<b>Purpose</b> First aid antiseptic
<b>First Aid Antiseptic</b>	<b>Uses</b> first aid to help prevent infection in minor cuts, scrapes and burns
Net contents 2 fl oz (59 mL)	<b>Warnings</b> For external use only
ANSI Z398.1-2003	<b>Do not use</b> • in or near the eyes • over large areas of the body
	<b>Ask a doctor before use if you have</b> • deep or puncture wounds • animal bites • serious burns
8 21812 01498 2	<b>When using this product</b> do not use longer than one week unless directed by a doctor
	<b>Stop use and ask a doctor if</b> condition persists or gets worse
	<b>Keep out of reach of children.</b> If swallowed get medical help or contact a Poison Control Center right away.
	<b>Directions</b> • clean the affected area • spray a small amount of this product on the area 1 to 3 times daily • may be covered with a sterile bandage • If bandaged, let dry first
	<b>Other information</b> • shake well • store at room temperature, 15° to 30°C (59° to 86°F)
	<b>Inactive ingredients</b> diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, triethylamine, water
	<b>Questions or comments?</b> 1-800-430-5490
	Mfg. for: Honeywell Safety Products USA, Inc. Smithfield, RI 02917 032203 Rev. G

## Ammonia Principal Display Panel

796006 Rev. E Unit Carton Printing Plate for "A" size carton.



Principal Display Panel



4244 Kit Label  
340410FP

**First Aid**

**4244 Kit Contnets**  
**340410FP**

- 1 INSTANT COLD PACK 4" X 6"
- 1 PVP IODINE WIPES 10 PER
- 1 ADH TAPE W/P 1/2"X 2 1/2 YD
- 1 FIRST AID GUIDE ASHI
- 1 GAUZE CLEAN-WRAP BDGE N/S 2"
- 1 FIRST AID SPRAY AEROSOL 3 OZ
- 1 ASPIRIN 5 GR BTL OF 100'S
- LBL STOCK 6-3/8"X4"
- LBL STOCK 4"X2-7/8"
- 1 LBL STOCK 3"x1-7/8"
- 1 PR LRG NITRILE GLVES ZIP BAG
- 1 1" X 3" PLASTIC BANDS 16/BAG
- 4 WIPE ALCOHOL PREP IPA 70% (DUKAL)
- 1 KIT STL 10 UN WHITE 01
- 4 NON ADHERENT PAD 2" X 3"
- 2 AMMONIA INHALANT, BULK

4244 FIRST AID KIT

4244 first aid kit kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0498-4244

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4244-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 POUCH	1.6 mL
Part 2	10 POUCH	3 mL
Part 3	1 BOTTLE, SPRAY	59 mL
Part 4	2 AMPULE	0.6 mL
Part 5	50 PACKET	100

Part 1 of 5

# ALCOHOL WIPE

isopropyl alcohol swab

## Product Information

Item Code (Source) NDC:0498-0143

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2018	

## Part 2 of 5

# PVP IODINE WIPE

povidone-iodine 10% swab

## Product Information

Item Code (Source) NDC:0498-0121

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 3 of 5
ANTISEPTIC
benzalkonium chloride spray

Product Information	
Item Code (Source)	NDC:0498-0402
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0402-59	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/18/2018	

Part 4 of 5
<b>AMMONIA INHALENT</b> ammonia inhalent inhalant

Product Information	
Item Code (Source)	NDC:0498-3334
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety		
Ingredient Name		Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)		0.045 g in 0.3 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-3334-00	0.3 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 5 of 5
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# ASPIRIN

aspirin tablet

## Product Information

Item Code (Source) NDC:0498-0114

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	FR21
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0114-01	2 in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/19/2018	



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

**Labeler** - Honeywell Safety Products USA, INC (079287321)

Establishment			
Name	Address	ID/FEI	Business Operations
James Alexander		040756421	manufacture(0498-3334)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4244)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-0114)

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0402)

Establishment			
Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)

Establishment			
Name	Address	ID/FEI	Business Operations
Sion Biotext Medical		532775194	manufacture(0498-0121)

Revised: 4/2019

Honeywell Safety Products USA, INC